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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MYERS, CARLA J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 12/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/644,349	SHIMKETS, RICHARD A.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Prior to setting forth the restriction requirement, it is pointed out that Applicants have presented claims 14, 15 and 25 in improper Markush format. See Ex parte Markush, 1925 C.D. 126 and In re Weber, 198 USPQ 334. The claims are improperly joined as the claimed methods require the detection or administration of distinct target molecules. A reference against one target molecule would not be a reference against the other target molecule. Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because the claims do not recite proper species. Upon election, Applicants are required to amend the claims to set forth only the elected inventive groups.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, drawn to methods of detecting a mutation in the FGF20 gene, classified in class 435, subclass 6.

II. Claims 6-8, drawn to methods for detecting a mutation in the FGF20 protein, classified in class 435, subclass 7.2.

III. Claims 9-14, drawn to methods for detecting the level of FGF20 protein as indicative of a hypophosphatemic condition, classified in Class 435, subclass 7.1.

IV. Claim 14, drawn to methods for detecting the level of FGF20 mRNA as indicative of a hypophosphatemic condition, classified in Class 435, subclass 6.

V. Claims 15 and 16, drawn to methods of treating a hypophosphatemic condition by administering a compound that reduces the level of FGF20 mRNA, classified in Class 514, subclass 44.

VI. Claims 15 and 16 , drawn to methods of treating a hypophosphatemic condition by administering a compound that reduces the level of FGF20 polypeptides, classified in Class 424, subclass 131.1. Note that further classification cannot be provided without additional details regarding the structure of the compound.

VII. Claims 15 and 16, drawn to methods of treating a hypophosphatemic condition by administering a compound that inhibits the activity of FGF20 polypeptides, classified in Class 514, subclass 1. Note that further classification cannot be provided without additional details regarding the structure of the compound.

VIII. Claims 17 and 18, drawn to methods of treating a hyperphosphatemic condition by administering FGF20 nucleic acids, classified in Class 514, subclass 44.

IX. Claims 19, 20 and 25, drawn to methods of treating a hyperphosphatemic condition by administering FGF20 polypeptides, classified in Class 514, subclass 1. Note that further classification cannot be provided without additional details regarding the structure of the compound.

X. Claims 21, 22 and 25, drawn to methods of treating a hyperphosphatemic condition by administering a compound that increases the level of FGF20

polypeptides, classified in Class 514, subclass 1. Note that further classification cannot be provided without additional details regarding the structure of the compound.

XI. Claims 23 and 24, drawn to methods of treating a hyperphosphatemic condition comprising administering a population of cells comprising FGF20 nucleic acids, classified in Class 424, subclass 93.1.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I-XI are drawn to patentably distinct inventions. Each invention is drawn to a distinct method which involves the use of different reagents, involves performing different method steps and have different outcomes or objectives. In particular, invention I requires the use of molecules which bind to and detect a mutation, and involves performing method steps of contacting a nucleic acid with a molecule that binds to and detects the presence of a mutation in a nucleic acid in order to accomplish the objective of diagnosing a hypophosphatemic condition. The method of invention II requires the use of an agent that binds to and detects the presence of a mutation in a polypeptide, and involves contacting a biological sample with said agents, and detecting binding between the agent and FGF20 polypeptides in order to accomplish the objective of diagnosing a hypophosphatemic condition. The method of invention III requires the use of an agent that detects wildtype FGF20 polypeptides and involves performing method steps which determine the level of FGF20 polypeptides in order to accomplish the objective of diagnosing a hypophosphatemic condition. The method of invention IV requires the use of an agent that detects wildtype FGF20 nucleic acids and involves

performing method steps which determine the level of FGF20 nucleic acids in order to accomplish the objective of diagnosing a hypophosphatemic condition. The method of invention V requires the use of an agent that decreases the level of FGF20 nucleic acids and involves treating a mammal with said agent in order to accomplish the objective of treating a hypophosphatemic condition. The method of invention VI requires the use of an agent that decreases the level of FGF20 polypeptides and involves treating a mammal with said agent in order to accomplish the objective of treating a hypophosphatemic condition. The method of invention VII requires the use of an agent that inhibits the activity of FGF20 proteins and involves treating a mammal with said agent in order to accomplish the objective of treating a hypophosphatemic condition. The method of invention VIII requires the use of a FGF20 nucleic acid and requires administering said nucleic acid to a mammal in order to accomplish the objective of treating a hyperphosphatemic condition. The method of invention IX requires the use of a FGF20 protein and requires administering said protein to a mammal in order to accomplish the objective of treating a hyperphosphatemic condition. The method of invention X requires the use of an agent that increases the level of a FGF20 protein and requires administering said agent to a mammal in order to accomplish the objective of treating a hyperphosphatemic condition. The method of invention XI requires the use of a population of cells comprising a FGF20 nucleic acid and requires administering said population of cells to a mammal in order to accomplish the objective of treating a hyperphosphatemic condition. The methods of invention I-XI are novel and unobvious over each other.

4. Further, should Applicants elect inventions V, VI or VII, these groups are subject to an additional restriction requirement as follows.

Claim 16 is subject to an additional restriction since this claim is not considered to recite a proper genus/Markush group.

Specifically, claim 16 recites the use of distinct inhibitors selected from the group consisting of antisense nucleic acids, ribozymes, antibodies, small molecules, peptides and peptidomimetic molecules. Each of these molecules consists of a different chemical structure, has a different mechanism of action and different effects. Given the differences in structure and function, the Markush group set forth in claim 16 is not considered to constitute a proper genus, and therefore is subject to a further restriction requirement. A sequence search and non-patent literature search of these distinct inhibitors would not be co-extensive with one another. For example, a search for methods of treatment which use antisense nucleic acids would not be co-extensive with a search for methods of treatment which use, for instance, ribozymes or antibodies. Accordingly, a search of more than one of the inhibitors as claimed in claim 16 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and the corresponding examination of more than one of the claimed sequences. Accordingly, Applicants are required to elect one inhibitor selected from the group consisting of antisense nucleic acids, ribozymes, antibodies, small molecules, peptides and peptidomimetic molecules. Note that this is not a species election.

Claim 15 links the individual inhibitors of claim 16, each inhibitor comprising a distinct invention as outlined above. The restriction requirement between the linked

inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.0.

5. These inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter. Further, inventions I-XI require different searches that are not co-extensive. For instance, a keyword / literature search for the methods of diagnosing a hypophosphatemic condition by assaying for a mutation in the FGF20 gene are distinct from, e.g., methods for diagnosing a hypophosphatemic condition by assaying for the level of wildtype FGF20 nucleic acids or methods for treating a hyperphosphatemic condition by administering a FGF20 nucleic acid. Further, a finding that the method of invention I is anticipated or obvious over the prior art would not necessarily extend to a finding that the method of inventions II-XI were also anticipated or obvious over the prior art. Similarly, a finding that the method of invention I is novel

and unobvious over the prior art would not necessarily extend to a finding that the methods of invention II-XI are also novel and unobvious over the prior art. Accordingly, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571)-272-0745.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

Carla Myers
December 12, 2005

CARLA J. MYERS
PRIMARY EXAMINER